REMARKS

In the Office Action dated June 3, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following inventions:

Groups I-XXIX	Claims 8-10, 21-23, 34-36, 47-49, 58-60 and 68-70, drawn to an isolated nucleic acid comprising SEQ ID NO: 3 through SEQ ID NO: 29, classified in class 536, subclass 23.1.

The Examiner states that claims 1, 15, 28, 40, 50 and 61 link inventions of Groups I-XXIX, and the restriction requirement is subject to the rejection of these linking claims. Therefore, upon the allowance of the linking claims, the restriction requirement shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

In support of the Restriction Requirement, the Examiner states that Groups I-XXIX are drawn to different and independent sequences which do not render each other obvious and thus are patentably distinct. The Examiner requires the applicants to elect a single invention which is drawn to one specific sequence to which the claims will be restricted. The Examiner states that this restriction to examination of a single sequence is due to the high and undue burden for examining more than one sequence in an application. The Examiner further states that claims 11-14, 25-27, 37-39 and 71-74, which are dependent claims, will be examined, subject to the election of the independent claims from which they depend, in any Group elected.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, claims 8-10, 21-23,

34-36, 47-49, 58-60 and 68-70, directed to nucleic acid molecules comprising SEQ ID NO: 3. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present case, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. More specifically, nucleic acid molecules comprising a sequence as set forth in SEQ ID NO: 3-29, as presently claimed, all relate to a nucleic acid molecule which, when activated, functions as a centromere. Specifically, SEQ ID NO: 3 sets forth the sequence of the HC-contig for human chromosome 10, i.e., the neocentromere located at or around human chromosome 10q25. SEQ ID NO: 4 sets forth the sequence of NC-contig from mardel (10), i.e., the region of chromosome 10 from the patient BE which comprises a neocentromere. SEQ ID NOS: 5-29 set forth the sequences of separate contigs of the p' region (F-2) of mardel (10) neocentromere. It is respectfully submitted that isolated nucleic acid molecules comprising

any of SEQ ID NOS: 3-29 are not independent, but are related to each other as different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to

legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner

reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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